XPECT DECONGESTANT- phenylephrine tablet Cintas Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Xpect Decongestant

Phenylephrine HCI 5mg

Active ingredients (in each tablet):
Phenylephrine HCl 5mg......Nasal Decongestant

Temporarily relieves nasal congestion due to:

- Common cold, hay fever or other upper respiratory allergies
- Sinus congestion and pressure helps decongest sinus openings and passages
- Temporarily restores free breathing through the nose

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- 3. Warning(s) (c)(5)

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping MAOI drug. If you do not know if your prescription drug contains an MAOI, consult a doctor or pharmacist before taking this product.

Ask a doctor before use if you have:

- Heart disease
- High blood pressure
- Thyroid disease
- Diabetes
- Trouble urinating due to enlarged prostate gland

When using this product do not exceed recommended dose

Stop using and ask doctor if:

- Nervousness, dizziness or sleeplessness occur
- Symptoms do not improve within 7 days or are accompanied by fever
- New symptoms occur

If pregnant or breast-feeding, ask health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

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Adults and children 12 years of age and older: Take 2 tablets every 4 hours not to exceed 8 tablets in 24 hours, unless directed by a doctor.

Children under 12 years of age: Ask a doctor.

- Do not use if package is torn, cut, or opened
- Store at room temperature $59 \square 86 \square F$ ($15 \square 30 \square C$)
- Avoid excessive heat and humidity

crosscarmellose sodium, D&C Red #27, dicalcium phosphate, Hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, starch, stearic acid



XPECT DECONGESTANT

phenylephrine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961-205
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	5 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
PHOSPHATE ION (UNII: NK08V8K8HR)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code		
Contains				

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:42961-205- 02	80 in 1 BOX	02/27/2021			
1	NDC:42961-205- 01	2 in 1 PACKET; Type 1: Convenience Kit of Co-Package				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/27/2021	

Labeler - Cintas Corporation (056481716)

Revised: 4/2021 Cintas Corporation